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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,500	12/09/2003	David M. Hardin JR.	10000/227	4634

7590 07/06/2007  
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EXAMINER

NGUYEN, HUONG Q

ART UNIT PAPER NUMBER

3736

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07/06/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/731,500		HARDIN ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Helen Nguyen		3736	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 January 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12, 15, 16, 18-21, 25-29, 53-63, 69, 70, 72-75 and 79-83 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12, 15, 16, 18-21, 25-29, 53-63, 69, 70, 72-75 and 79-83 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 December 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/9/2004, 4/5/2004, 5/9/2005</u>                              | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election of Group 1, Species 1 in the reply filed on 1/3/2007 is acknowledged. Applicant's later election of Species 4 and 7 is also acknowledged by phone to complete the formerly incomplete election response. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 13-14, 17, 22-24, 30-52, 64-68, 71, 76-78, and 84-107 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group and invention. Election was made **without** traverse. **Claims 1-12, 15-16, 18-21, 25-29, 53-63, 69-70, 72-75, and 79-83** remain pending.
3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### *Priority*

4. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged, namely, priority as a continuation-in-part (CIP) to application 10/699487, now US Pat No. 6976955 filed on 10/31/2003, which claims benefit to provisional application 60479709 filed on 6/19/2003.

***Information Disclosure Statement***

5. The information disclosure statement (IDS) submitted on 1/9/2004, 4/5/2004, and 5/9/2005 is/are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

6. It is noted that the list of references submitted on 1/30/2004 has not been considered because the information disclosure statement fails to comply with 37 CFR 1.98(a)(1), which requires the following: (1) a list of all patents, publications, applications, or other information submitted for consideration by the Office; (2) U.S. patents and U.S. patent application publications listed in a section separately from citations of other documents; (3) the application number of the application in which the information disclosure statement is being submitted on each page of the list; (4) a column that provides a blank space next to each document to be considered, for the examiner's initials; and (5) a heading that clearly indicates that the list is an information disclosure statement. The information disclosure statement has been placed in the application file, but the information referred to therein has not been considered.

7. It is noted that the presentation noted in the IDS dated 1/9/2004 has not been considered because applicant has not provided a copy therein.

***Drawings***

8. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the finger-loop handle, pin-vice handle, or half-finger loop handle of **Claims 15 and 69** as well as the marker of **Claims 25 and**

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79 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international

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application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. **Claims 1-2, 7, 9-11, 20, and 29** are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Reeves et al (US Pat No. 7056293).

11. In regards to **Claim 1**, Reeves et al disclose a medical apparatus comprising:

a needle 12 having a proximal end, a distal end, and an inner lumen extending from said proximal end to said distal end, best seen in Figure 3;

a stylet 16 having a proximal end and a distal end, wherein said stylet is adapted to be inserted into and withdrawn from said inner lumen of said needle with at least a portion of said stylet adapted to plug said inner lumen of said needle when a cytology sample is cut (Col.3: 27-35);

a cytology collection device 48 having a proximal end and a distal end, wherein said cytology collection device is adapted to be inserted into said inner lumen of said needle when said stylet is withdrawn from the inner lumen of said needle, with said distal end of said cytology collection device adapted to extend beyond the distal end of said needle in order to collect said cytology sample, best seen in Figure 2 (Col.4: 45-55).

12. In regards to **Claims 2**, Reeves et al disclose said cytology collection device 48 comprises an elongate member having a proximal end, a distal end, and a plurality of bristles (Col.4: 22-28).

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13. In regards to **Claim 7**, Reeves et al disclose the distal end of the elongate member is adapted to be retracted within the inner lumen of said needle after collecting said cytology sample.

14. In regards to **Claim 9**, Reeves et al disclose said plurality of bristles is made of one or more of nylon, brass, stainless steel, metal, carbon, and polymer (Col.4: 25-27).

15. In regards to **Claim 10**, Reeves et al disclose said needle 12 is capable and thus adapted to provide suction.

16. In regards to **Claim 11**, Reeves et al disclose a handle 20 which is adapted to provide axial movement of said cytology collection device 48 and said needle 12, best seen in Figure 3.

17. In regards to **Claim 20**, Reeves et al disclose said stylet 16 is a solid rod used to plug said needle.

18. In regards to **Claim 29**, Reeves et al disclose an outer surface of said stylet 16 has a first diameter and an inner surface of said needle 12 has a second diameter slightly larger than said first diameter, wherein said outer surface of said stylet is adapted to contact said inner surface of said needle to plug said inner lumen of said needle while said cytology sample is cut (Col.3: 31-34).

***Claim Rejections - 35 USC § 103***

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

20. **Claims 3-6, 8, 21, 26-28, 53-62, 74-75, and 80-83** are rejected under 35 U.S.C. 103(a) as being unpatentable over Reeves et al in view of Wang (US Pat No. 4966162).

21. In regard to **Claims 3-6**, Reeves et al disclose the cytology collection device 48 above but do not explicitly disclose the structure and material of its distal end nor the structure and material of its elongate member. Wang discloses an analogous cytology collection device 176, 230 having a distal end terminating in a loop 232 and comprises a wire 170 twisted around a plurality of bristles 178, best seen in Figures 6 and 11. Wang also discloses said cytology collection device made of steel (Col.6: 10-24). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the cytology collection device of Reeves et al to have a distal end terminating a loop and also comprising a wire twisted around a plurality of bristles and said distal end and said wire made of steel as taught by Wang as an effective configuration and make of said cytology collection device for the purpose of sampling.

22. In regard to **Claims 8 and 21**, Reeves et al disclose the needle 12 and stylet 16 above but do not specify the material. Wang discloses an analogous device made of steel (Col.8: 35-36) as an effective material used for tissue sampling. Therefore, it would have been obvious to one of



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ordinary skill in the art at the time the invention was made to make the needle and style of Reeves et al out of steel as taught by Wang as a desirable material used for such sampling device.

23. In regard to **Claims 26-27**, Reeves et al disclose the stylet 16 above but do not disclose said style adapted to cut said cytology sample. Wang teaches an analogous style 140 having a sharp distal end 174, best seen in Figure 3 and 6 to cut a cytology sample allowing greater range of sampling (Col.6: 47-53). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the stylet of Reeves et al with a sharp distal end adapted to cut a cytology sample as taught by Wang to allow penetration of cysts and other tissue for a greater sampling range.

24. In regards to **Claim 28**, Reeves et al in combination with Wang disclose said distal end of said stylet 16 is adapted to extend beyond the distal end of said needle 12.

25. In regard to **Claims 53 and 80-82**, Reeves et al disclose a method for collecting a cytology sample from a mammalian body comprising:

providing an apparatus comprising: a needle 12 having a proximal end, a distal end, and an inner lumen extending from said proximal end to said distal end; a stylet 16 having a proximal end and a distal end; a cytology collection device 48 having a proximal end and a distal end for cytology collection;

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inserting said stylet into said inner lumen of said needle, wherein at least a portion of said stylet plugs said inner lumen of said needle (Col.3: 31-34);

withdrawing said stylet from said inner lumen of said needle (Col. 4: 45-47);

inserting said cytology collection device into said inner lumen of said needle so that said distal end of said cytology collection device extends beyond the distal end of said needle (Col.4: 54-55);

collecting said cytology sample from said mammalian body using said cytology collection device (Col.4: 55);

retracting said distal end of said cytology collection device into said inner lumen of said needle (Col.56-60).

26. However, Reeves et al do not disclose the method step of cutting an area within said mammalian body with said stylet. Wang teaches an analogous collection method including the step of cutting tissue to gain greater access into tissue for sampling (Col.2: 6-16). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Reeves et al to include the step of cutting an area within said mammalian body such as with the sharpened stylet to gain greater access to tissue for sampling.

27. In regard to **Claims 54, 60, 62, 74, and 83**, Reeves et al in combination with Wang disclose the claimed elements in the manner previously explained in the above rejections of Claims 2, 9, 11, 20, and 29 respectively.

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28. In regard to **Claims 55-58**, Reeves et al in combination with Wang disclose the claimed elements in the manner previously explained in the above rejections of Claims 3-6 respectively.

29. In regard to **Claims 59 and 75**, Reeves et al in combination with Wang disclose the claimed elements in the manner previously explained in the above rejections of Claims 8 and 21 respectively.

30. In regards to **Claim 61**, Reeves in combination with Wang disclose the method above but do not disclose the step of providing suction through said needle. Wang teaches that suction is advantageously used to effectively sample tissue during use (Col.4: 4-8). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Reeves as modified by Wang to include the step of providing suction through the needle to enhance the sampling process.

31. **Claims 12 and 25** are rejected under 35 U.S.C. 103(a) as being unpatentable over Reeves et al in view of Rabiner et al (US Pat No. 6579279).

32. In regards to **Claim 12**, Reeves et al disclose the handle 20 above but do not disclose said handle comprising an inner handle member, a first outer handle member, and an elongate sheath. Rabiner et al disclose an analogous device comprising an inner handle member 40 having a proximal end and a distal end; a first outer handle member 42 slideably disposed on the inner handle member; and an elongate sheath 26 attached to the inner handle member and axially

extending beyond the distal end of the inner handle member, the sheath defining a sheath lumen to allow a catheter 29 to be disposed in the sheath lumen, best seen in Figures 1-2. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the handle of Reeves et al to include an inner handle member, a first outer handle member, and an elongate sheath in the manner taught by Rabiner et al an effective arrangement that allows locking and relative movement and rotation of said handle members as well as the component disposed within the sheath, wherein in use it would be obvious to place the needle within the sheath lumen.

33. In regards to **Claim 25**, Reeves et al disclose the device above but do not disclose a marker near the proximal end of said cytology collection device which is adapted to indicate when said distal end of said cytology collection device has been extended beyond the distal end of said needle. Rabiner et al disclose markers 182 disposed on a proximal end best seen in Figure 3 to indicate when a catheter tip 28 has extended beyond the distal end of sheath 26 (Col.7: 24-28). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the device of Reeves et al a marker disposed on a proximal end such as on the cytology collection device to effectively indicate to the user when the distal end of the cytology collection device has extended beyond the distal end of the needle.

34. **Claim 15** is rejected under 35 U.S.C. 103(a) as being unpatentable over Reeves et al in view of Secrest et al (US Pat No. 7108661).

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35. Reeves et al disclose the handle 20 above but do not disclose said handle comprises one of a finger-loop handle, a pin-vice handle, and a half-finger loop handle. Secrest et al disclose an analogous device with a handle having a finger-loop 122 best seen in Figure 1 for ease of grip. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the handle of Reeves et al to have a finger-loop handle as taught by Secrest et al for ease of grip during use.

36. **Claim 16** is rejected under 35 U.S.C. 103(a) as being unpatentable over Reeves et al in view of Ishiguro (US Pat No. 6108439).

37. Reeves et al disclose the device above including an endoscope and a means for imaging the position of the cytology collection device but do not disclose the use of an ultrasound transducer to determine the position. Ishiguro teaches an ultrasound transducer 10 that emits ultrasound waves used to determine position (Col.11: 61-67; Col.12: 1-5). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to replace the imaging means of Reeves with the ultrasound transducer of Ishiguro as an equally as effective means to determine the position of said cytology collection device within the body.

38. In regards to **Claim 18**, Reeves et al in combination with Ishiguro disclose said cytology collection device comprises an elongate member having a proximal end, a distal end, and a plurality of bristles, wherein said transducer is adapted to emit ultrasound waves capable of reflecting off said plurality of bristles.

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39. In regards to **Claim 19**, Reeves et al disclose said plurality of bristles is made of one or more of nylon, brass, stainless steel, metal, carbon, and polymer (Col.4; 25-27).

40. **Claims 63 and 79** are rejected under 35 U.S.C. 103(a) as being unpatentable over Reeves et al in view of Wang, further in view of Rabiner et al in the manner previously explained in the above rejections of Claims 12 and 25.

41. **Claim 69** is rejected under 35 U.S.C. 103(a) as being unpatentable over Reeves et al in view Wang, further in view of Secrest et al in the manner previously explained in the above rejection of Claim 15.

42. **Claims 70 and 72-73** are rejected under 35 U.S.C. 103(a) as being unpatentable over Reeves et al in view Wang, further in view of Ishiguro in the manner previously explained in the above rejections of Claims 16 and 18-19.

### ***Conclusion***

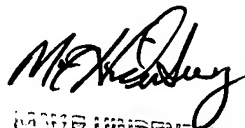
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen Nguyen whose telephone number is 571-272-8340. The examiner can normally be reached on Monday - Friday, 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

HQN  
6/25/2007

  
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